B5

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,612	02/26/2002	Marco Guida	4389-5-C1	8119

25106 7590 11/12/2004

GENAISSANCE PHARMACEUTICALS
5 SCIENCE PARK
NEW HAVEN, CT 06511

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,612	GUIDA ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18,22,25,26 and 35-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,22,25,26 and 35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0304*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to the Amendment and Response filed March 9, 2004, and the complying complete set of claims filed July 16, 2004. Claims 19-21, 23-24, and 27-34 have been canceled, claims 17-18, 22, and 25-26 have been amended, and claims 35-44 have been added. Claims 17-18, 22, 25-26, and 35-44 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. With regard to Application No. 60/271,630, it is noted that (as discussed in the Interview of February 24, 2004), the '630 application does provide basis for the claimed invention, and therefore the effective filing date of the claims is the filing date of that application (February 26, 2001).

Claim Rejections - 35 USC § 112

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:

3. Claims 17-18, 22, 25-26, and 35-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-18, 22, 25-26, and 35-44 are indefinite over the recitation of the limitation "G at a position corresponding to nucleotide 1037 in SEQ ID NO:4." It is

unclear as to what would be encompassed by this limitation. Specifically, how much of SEQ ID NO: 4 would have to be detected in order for one to conclude that a G "corresponding to nucleotide 1037 in SEQ ID NO:4" is present in a molecule (e.g., would one need to detect SEQ ID NO: 4 in its entirety? 20 nucleotides of flanking sequence? 50 nucleotides of flanking sequence?). Thus, this language does not clearly apprise one of skill in the art as to what would actually have to be determined/detected in order to meet the requirements of the claims.

Claims 17-18, 22, and 35-38 are indefinite over the recitation of the limitation "identifying the individual as having a predisposition for reduced metabolism of the CYP3A4 substrate or the CYP3A5 substrate if one or both of the G at position –392 of the promoter of the CYP3A4 gene with respect to the start codon of the CYP3A4 gene and the G at a position corresponding to nucleotide 1037 in SEQ ID NO:4 are determined to be present in the individual." It is noted that the claims are drawn to a method of screening "for predisposition for reduced metabolism of a CYP3A4 substrate or a CYP3A5 substrate" (see preamble of claim 17). However, the language of the final "identifying" step (recited above) refers to detection of one or both of the recited CYP3A4 nucleotide and the recited nucleotide in SEQ ID NO:4. It is not clear whether Applicants' intent is to indicate that detection of both nucleotides would be indicative only of predisposition for reduced metabolism of one of the CYP3A4 or CYP3A5 substrates, or whether the claims are intended to encompass embodiments in which, e.g., detection of both nucleotides would indicate a predisposition for reduced metabolism of both types of substrates. Further, it is not clear whether Applicants'

intent is to indicate that detection of either one of the recited CYP3A4 nucleotide or the recited nucleotide in SEQ ID NO:4 would be indicative of a predisposition for reduced metabolism of either the CYP3A4 or CYP3A5 substrate (such that, e.g., the CYP3A4 nucleotide could be indicative of a predisposition for reduced CYP3A5 substrate metabolism), or whether the claims are limited to methods in which the recited CYP3A4 nucleotide is indicative of CYP3A4 substrate metabolism, while the recited SEQ ID NO: 4 nucleotide is indicative of CYP3A5 substrate metabolism. Clarification is required.

Claims 25-26 and 39-44 are indefinite over the recitation of the limitations "conventional dose" and "higher than conventional dose." While Applicants' specification provides a general discussion of what might be included among conventional and "higher than conventional" doses of particular agents at, e.g., page 23, neither the specification nor the art provides any kind of definition for these terms that would apprise one of skill in the art as to how these terms actually limit the instant claims. Further, there is great variation in the art with respect to what doses of various agents might be considered "convention" and/or "higher than convention." Accordingly, it is not clear what dosages of various agents would be encompassed by the claims.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Primary Examiner
November 10, 2004